Australian Government
Department of Health and Aged Care
Office of the Gene Technology Regulator

October 2024

Risk Assessment and Risk Management Plan for

DIR 205

Limited and controlled release of canola genetically modified for increased abiotic stress tolerance

Applicant: CSIRO

October 2024

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Summary of the Risk Assessment and Risk Management Plan for Licence Application No. DIR 205

Decision

The Gene Technology Regulator (the Regulator) has decided to issue a licence for this application for the intentional release of a genetically modified organism (GMO) into the environment. A Risk Assessment and Risk Management Plan (RARMP) for this application has been prepared by the Regulator in accordance with the *Gene Technology Act 2000* (the Act) and corresponding state and territory legislation, and finalised following consultation with a wide range of experts, agencies and authorities, and the public. The RARMP concluded that the proposed field trial poses negligible risk to human health and safety and the environment and that any risks posed by the dealings can be managed by imposing conditions on the release.

The application

Applicant	CSIRO
Project title	Limited and controlled release of canola genetically modified for increased abiotic stress tolerance[1]
Parent organism	Canola (*Brassica napus* L.)
Introduced genes	• A gene from yeast[2] conferring abiotic stress tolerance • *pat* gene from *Streptomyces viridochromogenes* as a selectable marker conferring glufosinate herbicide tolerance
Proposed locations	Up to 3 sites per year in canola growing areas of New South Wales and South Australia
Proposed release size	Up to a maximum planting area of 1.5 hectares (ha) for each site in the first year and 2 ha for each site in the subsequent years
Proposed period of release	From May 2025 to December 2030
Principal purpose	To evaluate the performance of GM canola plants under field conditions with and without irrigation

Risk assessment

The risk assessment process considers how the genetic modification and proposed activities conducted with the GMOs might lead to harm to people or the environment. Risks are characterised in relation to both the seriousness and likelihood of harm, taking into account current scientific/technical knowledge, information in the application (including proposed limits and controls) and relevant previous approvals. Both the short- and long-term impacts are considered.

Credible pathways to potential harm that were considered included exposure of people or other desirable organisms to the GM plant material, potential for persistence or dispersal of the GMOs, and transfer of the

[1] The title of the project as supplied by the applicant is "Limited and controlled release of *Brassica napus* (Canola) genetically modified for increased physiological growth in response to abiotic stresses".

[2] Details about the identity and source of the introduced gene in the GM canola lines have been declared as Confidential Commercial Information (CCI) under section 185 of the Act. This information is made available to the prescribed experts and agencies during consultation on this application. CCI is not available to the public.

introduced genetic material to non-GM canola plants. Potential harms associated with these pathways included toxicity and allergenicity to people, toxicity to desirable animals, and environmental harms due to weediness.

The risk assessment concludes that risks to the health and safety of people or the environment from the proposed dealings are negligible. No specific risk treatment measures are required to manage these negligible risks. The principal reasons for the conclusion of negligible risks are that the proposed limits and controls, such as not using GM plant material in human food or animal feed, will effectively minimise exposure to the GMOs. In addition, there is no evidence to suggest the introduced genetic modifications could lead to harm to people or the environment.

Risk management plan

The risk management plan describes measures to protect the health and safety of people and to protect the environment by controlling or mitigating risk. The risk management plan is given effect through licence conditions.

As the level of risk is considered negligible, specific risk treatment is not required. However, since this is a limited and controlled release, the licence includes limits on the size, location and duration of the release, as well as controls to prohibit the use of GM plant material in human food and animal feed, to minimise dispersal of the GMOs or GM pollen from the trial site, to transport GMOs in accordance with the Regulator's guidelines, to destroy GMOs at the end of the trial and to conduct post-harvest monitoring at the trial sites to ensure the GMOs are destroyed.

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Abbreviations

5’ UTR	5’ untranslated region
APVMA	Australian Pesticides and Veterinary Medicines Authority
CCI	Confidential Commercial Information
DAFF	Department of Agriculture, Fisheries and Forestry
DIR	Dealings involving Intentional Release
FSANZ	Food Standards Australia New Zealand
GM(O)	Genetically modified (organism)
ha	Hectare(s)
HA-Tag	Peptide tag from human influenza hemagglutinin
HGT	Horizontal gene transfer
km	Kilometre(s)
m	Metre(s)
mm	Millimetre(s)
MAR	Matrix attachment region
NOS	Nopaline synthase
NSW	New South Wales
OGTR	Office of the Gene Technology Regulator
PAT	Phosphinothricin N-acetyltransferase
RARMP	Risk Assessment and Risk Management Plan
Regulations	Gene Technology Regulations 2001
Regulator	Gene Technology Regulator
SA	South Australia
TGA	Therapeutic Goods Administration
TMV	Tobacco mosaic virus
the Act	The *Gene Technology Act 2000*
Vic	Victoria
WA	Western Australia

Chapter 1 Risk assessment context

Section 1 Background

1. An application has been made under the *Gene Technology Act 2000* (the Act) for Dealings involving the Intentional Release (DIR) of genetically modified organisms (GMOs) into the Australian environment.

2. The Act and the Gene Technology Regulations 2001 (the Regulations), together with corresponding State and Territory legislation, comprise Australia's national regulatory system for gene technology. Its objective is to protect the health and safety of people, and to protect the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with GMOs.

3. Section 50 of the Act requires that the Gene Technology Regulator (the Regulator) must prepare a Risk Assessment and Risk Management Plan (RARMP) in response to an application for release of GMOs into the Australian environment. Sections 50, 50A and 51 of the Act and sections 9 and 10 of the Regulations outline the matters which the Regulator must take into account and who must be consulted when preparing the RARMP.

4. The *Risk Analysis Framework* (OGTR, 2013) explains the Regulator's approach to the preparation of RARMPs in accordance with the Act and the Regulations. The Regulator has also developed operational policies and guidelines that are relevant to DIR licences. These documents are available from the Office of the Gene Technology Regulator (OGTR) website.

5. Figure 1 shows the information that is considered, within the regulatory framework, in establishing the risk assessment context. This information is specific for each application. Potential risks to the health and safety of people or the environment posed by the proposed release are assessed within this context. Chapter 1 provides the specific information for establishing the risk assessment context for this application.

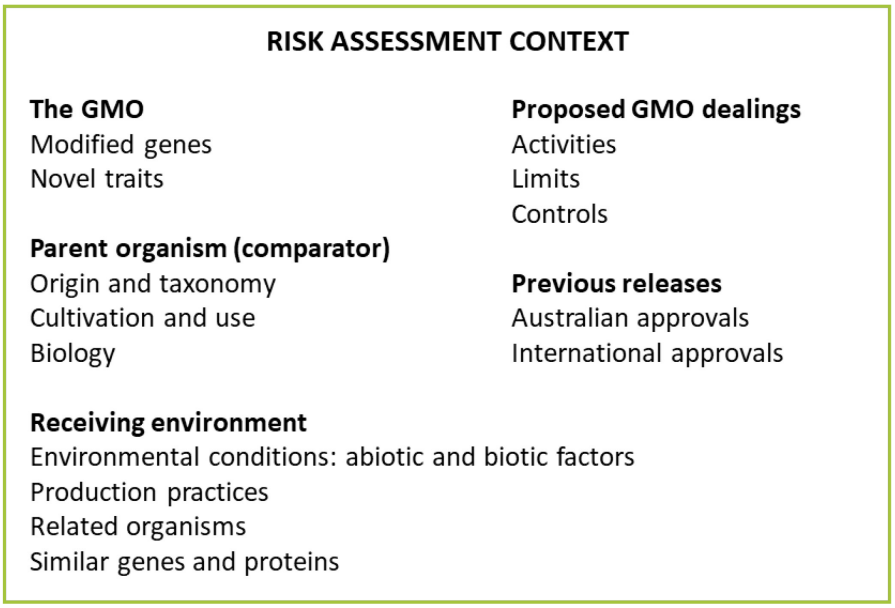

Figure 1. Summary of parameters used to establish the risk assessment context, within the legislative requirements, operational policies and guidelines of the OGTR, and the Risk Analysis Framework

6. In accordance with section 50A of the Act, this application is considered to be a limited and controlled release application, as the Regulator was satisfied that it meets the criteria prescribed by the Act. Therefore, the Regulator was not required to consult with prescribed experts, agencies and authorities before preparation of the RARMP.

1.1 Interface with other regulatory schemes

7. The GMOs and any proposed dealings may also be subject to regulation by other Australian government agencies that regulate GMOs or GM products, including Food Standards Australia New Zealand (FSANZ), the Australian Pesticides and Veterinary Medicines Authority (APVMA), the Therapeutic Goods Administration (TGA) and the Department of Agriculture, Fisheries and Forestry (DAFF). Proposed dealings may also be subject to the operation of State legislation declaring areas to be GM, GM free, or both, for marketing purposes.

8. To avoid duplication of regulatory oversight, risks that have been considered by other regulatory agencies will not be re-assessed by the Regulator.

Section 2 The proposed dealings

9. CSIRO (the applicant) proposes to release multiple GM canola lines into the environment under limited and controlled conditions. The GM plants have been genetically modified for increased abiotic stress tolerance.

10. The purpose of the release is to evaluate the performance of GM canola plants under field conditions with and without irrigation.

11. The dealings involved in the proposed intentional release are to:

- conduct experiments with the GMOs
- breed the GMOs
- propagate the GMOs
- grow the GMOs
- transport the GMOs
- dispose of the GMOs

and the possess, supply or use the GMOs in the course of any of these dealings.

12. GM plant material would not be used for human food or animal feed.

2.1 The proposed limits of the dealings (duration, size, location and people)

13. The release is proposed to take place between May 2025 and December 2030, at 3 trial sites located in New South Wales (NSW) and South Australia (SA). The proposed maximum number of sites, planting area per site and combined total planting area for each year are detailed in Table 1.

Table 1. Proposed duration and maximum number of sites and planting area per year

Year	Maximum number of sites per year	Maximum area (hectares) per site	Maximum combined area (hectares) per year
2025	3	1.5	4.5
2026 -2030	3	2	6

14. The release is proposed to take place at three trial sites:

- CSIRO's Agricultural Research Station, Boorowa, NSW
- University of Adelaide's GM field trial site, Rosedale, SA
- CSIRO's Myall Vale site, Narrabri, NSW.

15. Only trained and authorised staff would be permitted to deal with the GM plants.

2.2 The proposed controls to restrict the spread and persistence of the GMOs in the environment

16. The applicant has proposed a number of controls to restrict the spread and persistence of the GM canola and the introduced genetic material in the environment. These include:

- not locating the trial sites in flood prone areas;

- surrounding the planting area with pollen trap, monitoring zone and isolation zone, as shown in Figure 2;
- treating any non-GM canola plants grown in planting areas or pollen traps as if they are GMOs;
- after harvest, destroying GMOs not required for further evaluation or future trials;
- cleaning equipment used in connection with the GMOs as soon as practicable and before use for any other purpose;
- transporting and storing GMOs in accordance with the current Regulator's Guidelines for the Transport, Storage and Disposal of GMOs;
- post-harvest tilling of planting areas, pollen traps and other areas where GMOs were dispersed to encourage seed germination; and
- post-harvest monitoring of each trial site at least every 2 months for at least 12 months and until the site is free of volunteer canola plants for at least 6 months, with any volunteer plants destroyed prior to flowering.

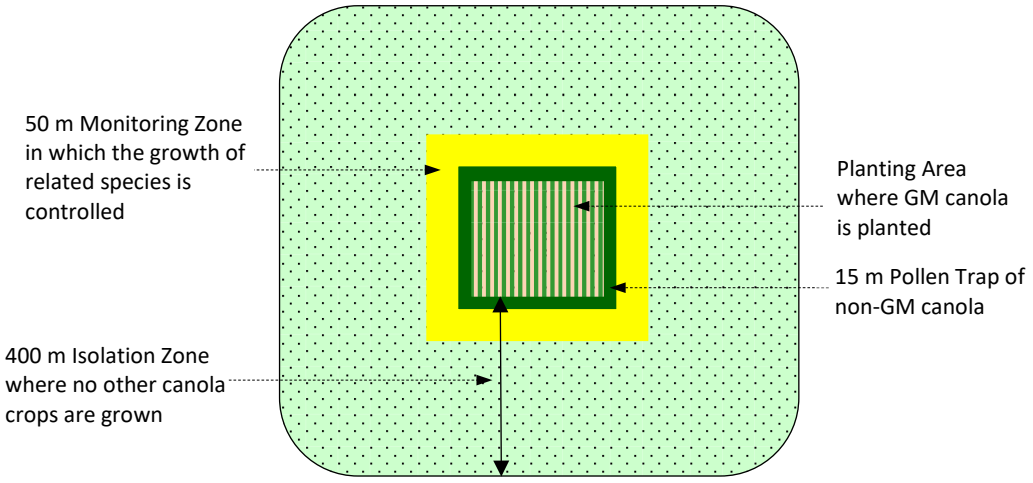

Figure 2. Proposed trial layout, including some of the controls (not to scale) and an access road of up to 3-4 m in width in the pollen trap to allow movement of vehicles and equipment to and from the Planting Area (not shown).

17. The proposed limits and controls are taken into account in the risk assessment (Chapter 2) and their suitability for containing the release will be evaluated in the risk management plan (Chapter 3).

Section 3 The parent organism

18. The parent organism is *Brassica napus* L., which is commonly known as canola, rapeseed or oilseed rape. *B. napus* is exotic to Australia.

19. Canola is the third-most widely grown crop in Australia. It is grown mainly in Western Australia (WA), NSW, Victoria (Vic) and SA (ABARES, 2024). Canola oil is used as food and the canola meal remaining after oil extraction is used as animal feed.

20. *B. napus* is naturalised in Australia. In areas where it is grown, it can be an agricultural weed in subsequent crops. There are isolated reports of *B. napus* as an environmental weed in WA and Vic (Randall, 2017). However, the most recent Western Australian state government environmental weed risk assessment gives *B. napus* a weed risk rating of negligible to low (Moore and Nazeri, 2022), and the most recent Victorian state government environmental weed list gives *B. napus* a risk ranking score of zero and classified as 'lower risk' (White et al., 2022).

21. Detailed information about the parent organism is contained in the document *The Biology of* Brassica napus *L. (canola)* and Brassica juncea *(L.) Czern. & Coss. (Indian mustard)* (OGTR, 2024), which was produced to inform the risk analysis process and is available from the Resources page on the OGTR website. Baseline information from this document will be used and referred to throughout the RARMP.

22. While non-GM canola is not generally regarded as allergenic or toxic to humans or animals, it does produce some toxins and anti-nutritional factors such as erucic acid and glucosinolates, and some cases of canola food, pollen and dust allergies have also been reported (OGTR, 2024).

23. Three canola inbred lines were used as the recipients for transformation to generate the GM canola lines proposed for this application. The identities of these inbred lines have been declared Confidential Commercial Information (CCI). Under section 185 of the Act, the confidential information is made available to the prescribed experts and agencies that are consulted on the RARMP for this application.

Section 4 The GMOs, nature and effect of the genetic modification

24. The applicant proposes to release 7 groups of canola genetically modified for increased abiotic stress tolerance.

4.1 The genetic modifications in the GMOs proposed for release

25. The GM canola lines contain an introduced gene from soil-borne yeast (designated as *GOI CDS 1.6*) or a truncated variant of this gene (designated as *GOI CDS 1.0*), intended to confer increased abiotic stress tolerance. Information about the identity and source of this gene has been declared CCI. Some GM canola lines may also contain one introduced selectable marker gene from a soil bacterium. Details of the genes are provided in Table 2.

Table 2. Introduced genes

Gene	Source organism	Encoded protein	Intended function
GOI CDS 1.6	Yeast	GTPase-activating protein	Abiotic stress tolerance
GOI CDS 1.0	Yeast	GTPase-activating protein	Abiotic stress tolerance
pat	*Streptomyces viridochromogenes*	Phosphinothricin N acetyltransferase (PAT)	Selectable marker (herbicide tolerance)

26. The purpose of the introduced *GOI CDS 1.6* or *GOI CDS 1.0* genes is to confer increased yield/biomass in the GM canola under abiotic stress conditions such as drought when the *GOI CDS 1.6* gene or the truncated *GOI CDS 1.0* gene are overexpressed under the control of constitutive promoters and various enhancers.

27. The *GOI CDS 1.6* gene encodes a GTPase-activating protein, which is involved in multiple cellular processes including nucleocytoplasmic transport, spindle assembly, and nuclear envelope (NE) formation. It is known as a shuttle transport factor which, together with exportins and importins, facilitates nucleo-cytoplasmic trafficking. This protein is conserved in fungi, animals and plants.

28. The pathways in which the protein encoded by the *GOI CDS 1.6* gene are involved regulate plant growth and development and may contribute differentially to abiotic stress response in plants (i.e. some abiotic stress tolerance could be increased and some could be decreased). In plants, overexpression of downstream genes of the GOI may confer abiotic stress tolerance such as cold tolerance but may also play a role in conferring hypersensitivity to salt and osmotic stress. In the model plant *Arabidopsis*, it was demonstrated that a similar gene is involved in the control of elongation growth by modulating the GA signalling pathway. It was previously shown that elevated expression of fungal or plant derived genes similar to *GOI CDS 1.6* significantly increased shoot weight in *Arabidopsis*.

29. The GMOs may also contain the *pat* selectable marker gene, which was used during initial development of the GM plants in the laboratory to select plant cells containing the introduced genes. The *pat* gene encodes the PAT enzyme that confers tolerance to glufosinate (phosphinothricin) herbicide.

30. Short regulatory sequences that control expression of the genes are also present in the GM canola lines (Table 3). The expression of the GOI and the selectable marker gene *pat* is driven by a constitutive promoter, which is active in all plant tissues. Other short regulatory elements used include enhancers for gene expression, terminators and other sequences with functions shown in Table 3.

31. A short sequence encoding a peptide tag (HA-tag) will also be present in some GM canola lines (Table 3). HA-tag is derived from amino acids 98–106 of human influenza hemagglutinin (HA) and is a strong immunoreactive epitope making it popular to isolate, purify, detect and track the protein of interest (Zhao et al., 2013). These 9 amino acids (YPYDVPDYA) are located in the subunit interface in the native HA trimeric structure and therefore is relatively inaccessible in the native HA conformation (Wilson et al., 1984). The HA-tag fused to a carrier protein was shown to be able to induce immune responses in animals when emulsified in a suitable adjuvant (Chiarella et al., 2010). Due to their small size, peptide tags, including the HA-tag, generally do not disturb protein function (Thermo Fisher Scientific Inc.). A search of the scientific literature found no reports of adverse immunogenic reactions to HA-tags fused to proteins.

Table 3. Introduced regulatory sequences and tag sequence

Genetic element	Source	Intended function
PRO_35S or 2×35S	Promoter of cauliflower mosaic virus gene encoding the 35S RNA	Constitutive promoter
5' UTR leader	Enhancer from the GOI	Increase gene expression
MAR_Nicta- RB7	Rb7 matrix attachment region from *Nicotiana tabacum*	Increase gene expression and reduce gene silencing
TER_Agrtu-NOS	Terminator of *Agrobacterium tumefaciens* nopaline synthase	Terminator
TER_Glyma-Lectin	Terminator of *Glycine max* lectin *Le1* gene	Terminator
TMV 5’ leader sequence	Tobacco mosaic virus	Enhancer
HA-Tag	Human influenza hemagglutinin (HA)	Detection of HA-tagged protein

4.2 Method of genetic modification

32. The GM canola lines were generated by *Agrobacterium*–mediated transformation. Information about this method can be found in the document Methods of plant genetic modification, available from the OGTR Risk Assessment References page.

33. Three parental inbred canola lines (Section 3) were transformed with 6 groups of binary plasmids. The details of the T-DNA constructs in these plasmids are shown in Figure 3. The constructs of pV3 and pV6 contain the *GOI CDS 1.6* and the *pat* genes, and the constructs of pV4 and pV5 contain the *GOI CDS 1.0* and the *pat* genes so the GOI and the selectable marker genes are in one T-DNA in these constructs for direct transformation.

34. The constructs p1.6 and p1.0 contain only *GOI CDS 1.6 and GOI CDS 1.0*, respectively, and the construct pPSM-PAT contains only the *pat* gene. The combination of p1.6 or p1.0 with pPSM-PAT were used for co-transformation. The transformants derived from co-transformation may be used for selection of GM canola lines containing only the *GOI CDS 1.6* or *GOI CDS 1.0* gene without the selectable marker gene. In addition, the constructs p1.6 and p1.0 only were also used for transformation to generate transformants without any selectable marker gene.

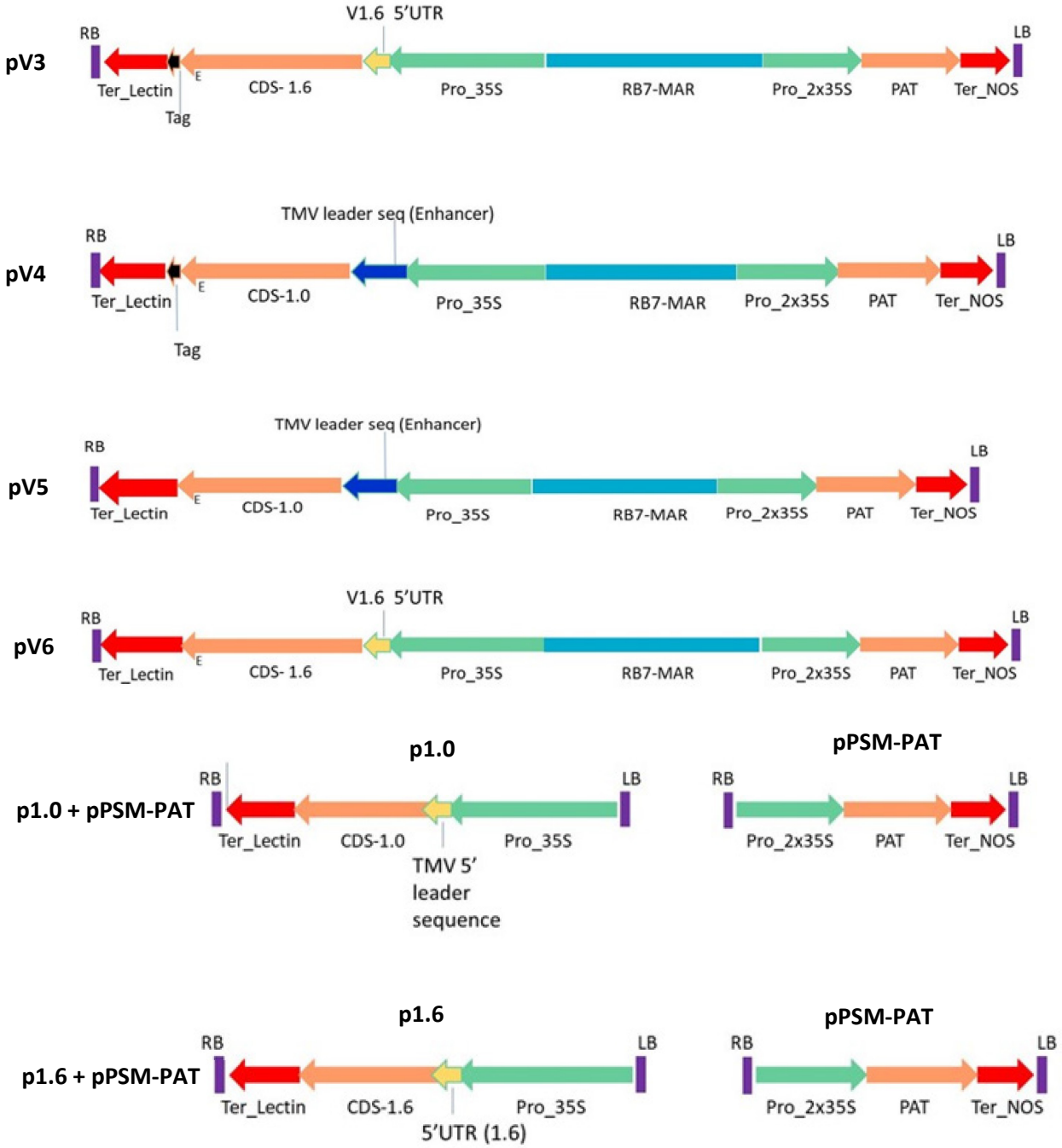

Figure 3. Constructs for direct transformation (pV3 to pV6) or co-transformation (p1.0 + pPSM-PAT and p1.6 + pPSM-PAT) (supplied by the applicant).

4.3 Toxicity/allergenicity of the proteins associated with the introduced genes

35. As the GMOs are at an early stage of development, no toxicity or allergenicity studies have been conducted on the GM canola plants or purified protein produced by the introduced *GOI CDS 1.6* or *GOI CDS 1.0.* These genes and their encoded proteins have also not been assessed by authorities in any countries for toxicity and allergenicity.

36. Bioinformatic analysis may assist in the assessment process by predicting, on a theoretical basis, the toxic or allergenic potential of a protein. The applicant has carried out bioinformatics studies on these proteins for any potential toxicity and allergenicity. The amino acid sequences encoded by both the *GOI CDS 1.6* and *GOI CDS 1.0* genes were analysed with CSM-Toxin prediction tool (https://biosig.lab.uq.edu.au/csm_toxin/). They were also compared to all proteins in the NCBI full non-redundant protein sequence database (http://www.ncbi.nlm.nih.gov/RefSeq/). The searches using the

CSM-Toxin prediction tool and the NCBI database did not find any biologically relevant similarity between the introduced proteins and known toxins. These amino acid sequences were also analysed using the database for allergens, AllergenOnline (V22) (http://allergenonline.org/). No matches of greater than 35% identity in the 80-mer window test for both amino acid sequences. This bioinformatics data suggests that the GOI does not produce an allergen or toxin.

37. As mentioned previously, the GOI is conserved across a broad evolutionary distance, from single-cell yeasts to plants and animals. Therefore, homologues of the expressed proteins and proteins with very similar function occur naturally in a range of organisms including those routinely consumed by humans and other desirable animals. Based on this, it is likely that people and other beneficial organisms have a long history of exposure to the proteins expressed by the introduced genes with no documented ill effect.

38. The *pat* gene and its products have been extensively characterised and assessed as posing negligible risk to human and animal health or to the environment by the Regulator, as well as by other regulatory agencies in Australia and overseas (CERA, 2011). Commercial GM canola lines containing the *pat* gene have been assessed to pose negligible risks to human health and the environment in the RARMPs for DIR 021/2002 (OGTR, 2003), DIR 108 (OGTR, 2011) and DIR 155 (OGTR, 2018).

4.4 Characterisation of the GMOs

39. Although the GM canola lines are at an early stage of development, the applicant has provided preliminary observations on some GM canola lines grown under glasshouse conditions. The applicant states that some GM lines showed increased plant height and total dry weight compared to their parental lines. Increased biomass and stem diameter was also observed but the percentage of these increases compared to the parental line was not quantified. In some T_0 lines, increased seed size was also observed.

40. The applicant indicates that homozygous GM canola lines will be used to quantify the changes in biomass, seed size and/or seed number in the GM plants. The applicant expects that the GM canola lines may perform better than the parental lines under abiotic stress conditions (such as drought) and this will be tested in the proposed field trial.

41. The applicant indicates that the T_1 and T_2 generations of the GM canola lines did not show any unexpected phenotype when grown in the glasshouse.

Section 5 The receiving environment

42. The receiving environment forms part of the context in which the risks associated with dealings involving the GMOs are assessed. Relevant information about the receiving environment includes abiotic and biotic interactions of the crop with the environment where the release would occur; agronomic practices for the crop; presence of plants that are sexually compatible with the GMOs; and background presence of the gene(s) used in the genetic modification (OGTR, 2013).

43. Detailed information about the commercial cultivation and distribution of canola in Australia is presented in the document *The Biology of* Brassica napus *L. (canola) and* Brassica juncea *(L.) Czern. & Coss. (Indian mustard)* (OGTR, 2024).

5.1 Relevant abiotic factors

44. The proposed release would occur at three trial sites in NSW and SA. The geographical distribution of commercial canola cultivation in Australia is limited by several abiotic factors, the most important being water availability. Canola is generally grown as a winter crop in winter-dominant medium and high rainfall environments that receive more than 350 mm rainfall per year (GRDC, 2009; OGTR, 2024). Germination of seed will only occur if there is sufficient soil moisture, and drought stress after anthesis can significantly reduce yield due to abortion of seed and reduced pod numbers. Canola is also sensitive to waterlogging (GRDC, 2009; OGTR, 2024). Other abiotic stresses that can reduce canola yields include frost, particularly during early pod development, and heat stress (GRDC, 2009).

5.2 Relevant biotic factors

45. A number of diseases have the potential to significantly reduce the yield of canola. Blackleg disease caused by the fungal pathogen *Leptosphaeria maculans* is the most serious disease affecting commercial canola production in Australia (GRDC, 2009; OGTR, 2024). Other damaging diseases of canola include stem rot caused by the fungus *Sclerotinia sclerotiorum* and damping-off, caused mainly by the fungus *Rhizoctonia solani* (GRDC, 2009, 2015).

46. Canola is most susceptible to insect pests during establishment of the crop, particularly from redlegged earth mite (*Halotydeus destructor*), blue oat mites (*Penthaleus major*, *P. falcatus* and *P. tectus* sp. n.), lucerne fleas (*Sminthurus viridis*), cutworms (*Agrotis* spp.) and aphids (*Brevicoryne brassicae*, *Myzus persicae, Lipaphis pseudobrassicae* and *Aphis craccivora*, also as viral vectors) (GRDC, 2009). From flowering to crop maturity, severe damage can be caused by aphids, Rutherglen bugs (*Nysius vinitor*), diamondback moth caterpillars (*Plutella xylostella*) and heliothis caterpillars (family Noctuidae).

47. Canola is highly susceptible to weed competition during the early stages of growth (GRDC, 2009, 2015). Hybrid canola have greater seedling vigour than open-pollinated canola and so are more competitive with weeds (GRDC, 2015, 2017). Common weeds of Australian canola crops include grassy weeds (such as rigid ryegrass, vulpia and wild oat), volunteer cereals, and weeds from the *Brassicaceae* family including wild radish (*Raphanus raphanistrum*), Indian hedge mustard (*Sisymbrium orientale*), shepherds purse (*Capsella bursa-pastoris*), Asian mustard (*Brassica tournefortii*), charlock (*Sinapis arvensis*), turnip weed (*Rapistrum rugosum*) and Buchan weed (*Hirschfeldia incana*) (GRDC, 2015, 2017).

5.3 Relevant agricultural practices

48. Agronomic and crop management practices for the cultivation of the GM canola by the applicant would be similar to that for commercial canola crops, except that the applicant proposes controls to restrict the dispersal and persistence of the GM canola (see Section 2.2). Standard cultivation practices for canola in Australia are discussed elsewhere (GRDC, 2015, 2017). The applicant proposes to only use the glufosinate tolerance conferred by the introduced *pat* gene as a selectable marker during transformation. Glufosinate herbicide is not intended to be applied to plants growing in the field trial.

49. The applicant specifies that the GM canola plants would be grown at field trial sites, either as an irrigated or dryland crop. Seed would be planted in rows with 17 to 25cm spacing, in either 3m, 5m or 10m lengths as individual rows or small plots. Small areas would be hand-planted or planted with a small plot cone-seeder; larger areas would be planted with commercial planting equipment.

50. Harvesting may occur by hand for small plantings or with commercial small plot harvesting equipment. Herbicides, pesticides, and pivot, linear, trickle tape, drip or furrow irrigation may be used as necessary to manage the health of the GM crop.

51. After leaving the location fallow during the off-season, it may be re-planted with the GM canola in the following growing season.

5.4 Presence of related species in the receiving environment

52. Canola is primarily self-pollinating, but approximately 30% of seeds are produced by cross-pollination (Hüsken and Dietz-Pfeilstetter, 2007). Cross-pollination can be mediated by insects, wind or physical contact (OGTR, 2024).

53. Canola has been reported to outcross in the field with the following species: *Brassica carinata*, *B. napus*, *B. juncea*, *B. oleracea, B. rapa*, *Hirschfeldia incana* (Buchan weed), *Raphanus raphanistrum* (wild radish) and *Sinapis arvensis* (charlock)(Ford et al., 2006; Warwick et al., 2009). All of these species are known to be present in Australia, with the exception of *B. carinata* (Atlas of Living Australia, accessed 5 June 2024).

54. Of the *Brassica* species in Australia, canola may potentially hybridise under natural conditions with sexually compatible species that include: other *B. napus* groups or subspecies (including vegetables such as swedes, rutabaga and kale), *B. juncea*, *B. rapa* (wild turnip; includes vegetables such as turnip, chinese

cabbage and pak choi) and *B. oleracea* (wild cabbage; includes vegetables such as cauliflower, Brussels sprouts and cabbage) (Salisbury, 2002). However, hybrids between *B. napus* and *B. oleracea* have been shown to be difficult to obtain (Ford et al. 2006).

55. Under open pollination conditions, naturally occurring hybrids between *B. napus* and the related weedy species *Raphanus raphanistrum*, *Hirschfeldia incana* and *Sinapis arvensis* have been reported at very low frequencies (Darmency and Fleury, 2000; Darmency et al., 1998; Salisbury, 2002), and are generally sterile or predominantly sterile (Salisbury, 2002).

56. Canola is widely grown as an oil seed crop in Australia, and the proposed trial sites are located in commercial canola growing regions. Commercial canola in these areas includes non-GM canola and GM canola authorised for commercial release. Most Australian canola crops are herbicide tolerant, with four different herbicide tolerance traits available for commercial cultivation: triazine tolerance (non-GM), imidazolinone tolerance (non-GM), glyphosate tolerance (GM), or glufosinate tolerance (GM) (Brown, 2021; Matthews et al., 2021). Details of all GM canola varieties approved by the Regulator for commercial release in Australia are available from the OGTR website.

5.5 Presence of similar genes and their products in the environment

57. The *GOI CDS 1.6* gene was derived from a soil-borne yeast that is widespread and prevalent in the environment. Homologues of the gene and encoded proteins occur naturally in yeast, as well as animals and plants including those routinely consumed by humans and other desirable animals, and it is likely that people and other beneficial organisms have a long history of exposure to the proteins expressed by the inserted genes.

58. The *pat* gene was obtained from the common soil bacterium *Streptomyces viridochromogenes.* The *pat* gene or the similar *bar* gene from *S. hygroscopicus* are also present in many types of GM canola or cotton authorised for commercial release in Australia (licences DIR 021/2002, DIR 062/2005, DIR 091, DIR 108, DIR 138, DIR 143, DIR 145, DIR 155, DIR 173, DIR 175 and DIR 178).

Section 6 Relevant Australian and international approvals

6.1 Australian approvals

Approvals by the Regulator

59. The GM canola lines included in this application have not been previously approved for release in Australia.

Approvals by other government agencies

60. The GM canola lines included in this application have not been previously approved by any other government agencies in Australia.

6.2 International approvals

61. The GM canola lines included in this application have not received any approvals from authorities in other countries.

Chapter 2 Risk assessment

Section 1 Introduction

62. The risk assessment identifies and characterises risks to the health and safety of people or to the environment from dealings with GMOs, posed by or as the result of gene technology (Figure 4). Risks are identified within the established risk assessment context (Chapter 1), taking into account current scientific and technical knowledge. A consideration of uncertainty, in particular knowledge gaps, occurs throughout the risk assessment process.

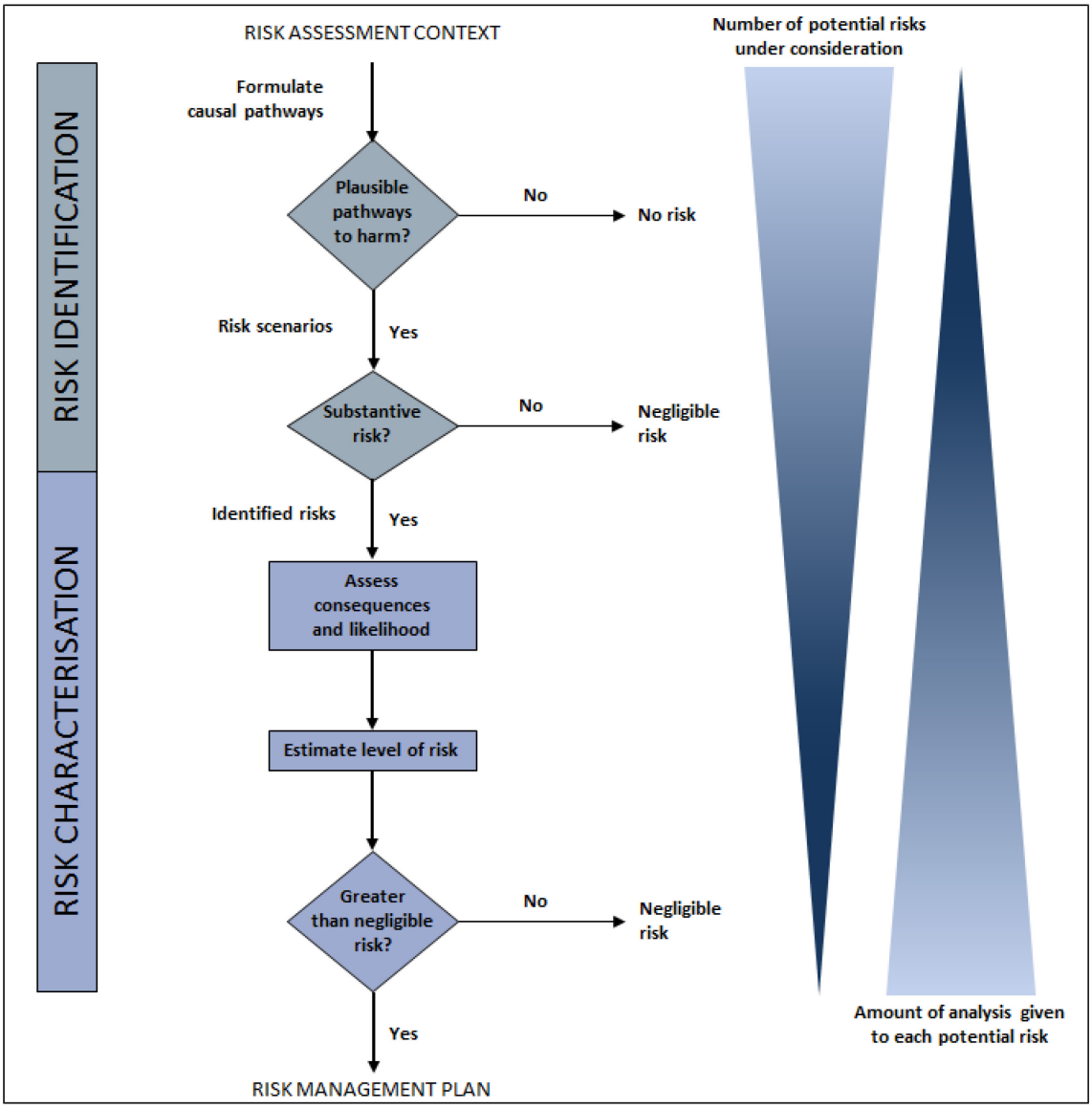

Figure 4. The risk assessment process

63. The Regulator uses a number of techniques to identify risks, including checklists, brainstorming, reported international experience and consultation (OGTR, 2013). A weed risk assessment approach is used to identify traits that may contribute to risks from GM plants, as this approach addresses the full range of potential adverse outcomes associated with plants. In particular, novel traits that may increase the potential of the GMO to spread and persist in the environment or increase the level of potential harm compared with the parental plant(s) are used to postulate risk scenarios (Keese et al., 2014). Risk scenarios examined in RARMPs prepared for licence applications for the same or similar GMOs are also considered.

64. Risk identification first considers a wide range of circumstances in which the GMO, or the introduced genetic material, could come into contact with people or the environment. This leads to postulating plausible causal pathways that may give rise to harm for people or the environment from dealings with a GMO. These are risk scenarios. These risk scenarios are screened to identify those that are considered to have a reasonable chance of causing harm in the short or long term. Pathways that do not lead to harm, or those that could not plausibly occur, do not advance in the risk assessment process (Figure 4), i.e., the risk is considered to be no greater than negligible.

65. Risks identified as being potentially greater than negligible are characterised in terms of the potential seriousness of harm (Consequence assessment) and the likelihood of harm (Likelihood assessment). Risk evaluation then combines the Consequence and Likelihood assessments to estimate the level of risk and determine whether risk treatment measures are required. The potential for interactions between risks is also considered.

Section 2 Risk identification

66. Postulated risk scenarios are comprised of three components (Figure 5):

i. the source of potential harm (risk source)

ii. a plausible causal linkage to potential harm (causal pathway)

iii. potential harm to people or the environment.

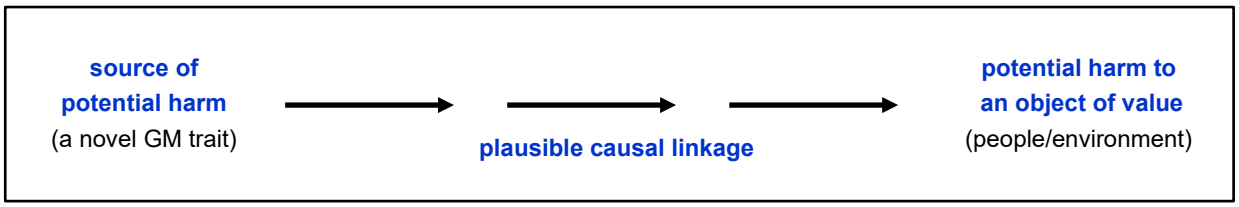

Figure 5. Risk scenario

67. When postulating relevant risk scenarios, the risk context is taken into account, including the following factors detailed in Chapter 1:

- the proposed dealings
- the proposed limits including the extent and scale of the proposed dealings
- the proposed controls to restrict the spread and persistence of the GMOs and
- the characteristics of the parent organism(s).

2.1 Risk source

68. The sources of potential harms can be intended novel GM traits associated with one or more introduced genetic elements, or unintended effects/traits arising from the use of gene technology.

69. As discussed in Chapter 1, the GM canola lines have been modified by the introduction of a gene or a variant of the gene from yeast. The introduced gene will be considered further as a source of potential harm.

70. Some of the constructs introduced into the GM canola lines also contain the HA-tag sequence from human influenza virus. As discussed in Chapter 1, Section 4.1, HA-tag is one of the widely used small peptide tags that does not generally disturb protein function. However, HA-tag is potentially immunogenic and will be considered further as a source of potential harm.

71. The GM canola lines may also contain the introduced *pat* gene which confers tolerance to glufosinate herbicide and was used as a selectable marker. The *pat* gene and its products have been extensively characterised and assessed as posing negligible risk to human and animal health or to the environment by the Regulator, as well as by other regulatory agencies in Australia and overseas (CERA, 2011). Commercial

GM canola lines containing the *pat* gene have been assessed to pose negligible risks to human health and the environment in the RARMPs for DIR 021/2002 (OGTR, 2003), DIR 108 (OGTR, 2011) and DIR 155 (OGTR, 2018). In addition, a herbicide tolerance trait has no effect except in an environment where the plant is exposed to the relevant herbicide, and it is unlikely that the proposed GM canola lines would be exposed to glufosinate herbicide in the field. This is because the applicant does not propose to use glufosinate during the field trial, glufosinate is not used to control volunteer canola (AOF, 2019), and although glufosinate is registered for weed control in summer fallows, it is more expensive and infrequently used compared to the alternative knockdown herbicides glyphosate and paraquat (Walsh, 2021). For these reasons, the *pat* gene will not be further considered as a source of potential harm.

72. The introduced genes are controlled by regulatory sequences. These were originally derived from plants, plant viruses and a bacterium (Table 3). Regulatory sequences are naturally present in all plants, and the introduced elements are expected to operate in similar ways to endogenous elements. These sequences are DNA that is not expressed as a protein, so exposure is to the DNA only and dietary DNA has no toxicity (Society of Toxicology, 2003). Hence, potential harms from the regulatory sequences will not be further assessed for this application.

73. Genetic modifications involving introduction of genes have the potential to cause unintended effects in several ways. These include insertional effects such as interruptions, deletions, duplications or rearrangements of the genome, which can lead to altered expression of endogenous genes. There could also be increased metabolic burden due to expression of the introduced proteins, novel traits arising out of interactions with non-target proteins and secondary effects arising from altered substrate or product levels in biochemical pathways. However, these types of effects also occur spontaneously and in plants generated by conventional breeding. Accepted conventional breeding techniques such as hybridisation, mutagenesis and somaclonal variation can have a much larger impact on the plant genome than genetic engineering (Schnell et al., 2015). Plants generated by conventional breeding have a long history of safe use, and there are no documented cases where conventional breeding has resulted in the production of a novel toxin or allergen in a crop (Steiner et al., 2013). Therefore, the potential for the processes of genetic modification to result in unintended effects will not be considered further.

Causal pathway

74. The following factors are taken into account when postulating plausible causal pathways to potential harm:

- routes of exposure to the GMOs, the introduced gene(s) and gene product(s)
- potential exposure to the introduced gene(s) and gene product(s) from other sources in the environment
- the environment at the site(s) of release
- agronomic management practices for the GMOs
- spread and persistence of the GMOs (e.g. reproductive characteristics, dispersal pathways and establishment potential)
- tolerance to abiotic conditions (e.g. climate, soil and rainfall patterns)
- tolerance to biotic stressors (e.g. pest, pathogens and weeds)
- tolerance to cultivation management practices
- gene transfer to sexually compatible organisms
- gene transfer by horizontal gene transfer (HGT)
- unauthorised activities.

75. Although all of these factors are taken into account, some are not included in risk scenarios because they have been thoroughly considered in previous RARMPs and a plausible pathway to harm could not be identified.

76. The potential HGT from GMOs to species that are not sexually compatible, and any possible adverse outcomes, have been reviewed in the literature (Keese, 2008; Philips et al., 2022) and assessed in many

previous RARMPs. HGT was most recently considered in the RARMP for DIR 108 (OGTR, 2011). HGT events rarely occur, and the wild-type gene sequences are already present in the environment and are available for transfer via demonstrated natural mechanisms. Therefore, no substantive risk was identified in previous assessments and HGT will not be further considered for this application.

77. Previous RARMPs have considered the potential for unauthorised activities to lead to an adverse outcome. The Act provides for substantial penalties for non-compliance and unauthorised dealings with GMOs. The Act also requires the Regulator to have regard to the suitability of the applicant to hold a licence prior to the issuing of a licence. These legislative provisions are considered sufficient to minimise risks from unauthorised activities, and no risk greater than negligible was identified in previous RARMPs. Therefore, unauthorised activities will not be considered further.

Potential harm

78. Potential harms from GM plants are based on those used to assess risk from weeds (Keese et al., 2014; Virtue, 2008) including:

- harm to the health of people or desirable organisms, including toxicity/allergenicity
- reduced biodiversity through harm to other organisms or ecosystems
- reduced establishment or yield of desirable plants
- reduced products or services from the land use
- restricted movement of people, animals, vehicles, machinery and/or water
- reduced quality of the biotic environment (e.g. providing food or shelter for pests or pathogens) or abiotic environment (e.g. negative effects on fire regimes, nutrient levels, soil salinity, soil stability or soil water table).

79. Judgements of what is considered harm depend on the management objectives of the land where the GM plant may be present. A plant species may have different weed risk potential in different land uses such as dryland cropping or nature conservation.

Postulated risk scenarios

80. Three risk scenarios were postulated and screened to identify any substantive risks. These scenarios are summarised in Table 4 and examined in detail in Sections 2.4.1 – 2.4.3.

81. In the context of the activities proposed by the applicant and considering both the short and long term, none of the three risk scenarios gave rise to any substantive risks.

Table 1. Summary of risk scenarios from the proposed dealings with GM canola

Risk scenario	Risk source	Causal pathway	Potential harm	Substantive risk?	Reason
1	Introduced genes for increased abiotic stress tolerance and the HA-tag	Cultivation of GM canola at trial sites ⬇ Exposure of people and desirable animals to products of the introduced genes	Increased toxicity or allergenicity for people OR increased toxicity to desirable animals	No	• The GM canola would not be used as human food or animal feed. • The small size and short duration of the proposed trial would restrict consumption of GM plant material by wild animals. • The limits and controls of the field trial would restrict exposure of people and desirable animals to the GM plants. • The proteins encoded by the introduced genes are not expected to be toxic or allergenic. • The HA-tag peptide present in GM canola is not expected to elicit strong immune responses.
2	Introduced genes for increased abiotic stress tolerance and the HA-tag	Cultivation of GM canola at trial sites ⬇ Dispersal of GM seed outside trial limits ⬇ Establishment of populations of volunteer GM plants expressing the introduced genes in the environment	Increased toxicity or allergenicity for people OR increased toxicity to desirable animals OR reduced establishment or yield of desirable plants	No	• The limits and controls of the field trial would minimise dispersal or persistence of GM seeds • GM canola is susceptible to standard weed management measures • As discussed in Risk Scenario 1, no substantive risk was identified for increased toxicity or allergenicity of the GM canola • Canola has limited ability to compete with other plants and the genetic modifications are not expected to increase the overall competitiveness of the GM canola
3	Introduced genes for increased abiotic stress tolerance and the HA-tag	Cultivation of GM canola at trial sites ⬇ Pollen from GM plants dispersed outside the trial sites ⬇ Outcrossing with sexually compatible plants ⬇ Establishment of populations of hybrid GM plants expressing the introduced genes in the environment	Increased toxicity or allergenicity for people OR increased toxicity to desirable animals OR reduced establishment or yield of desirable plants	No	• The controls of the field trial would minimise pollen flow to sexually compatible plants outside the trial sites • As discussed in Risk Scenario 1, no substantive risk was identified for increased toxicity or allergenicity of the GM canola • As discussed in Risk Scenario 2, the genetic modifications are not expected to increase the overall competitiveness of the GM canola with other plants

2.1.1 Risk scenario 1

Risk source	Introduced genes for increased abiotic stress tolerance and the HA-tag
Causal pathway	⬇ Cultivation of GM canola at trial sites ⬇ Exposure of people and desirable animals to products of the introduced genes ⬇
Potential harm	Increased toxicity or allergenicity for people OR Increased toxicity to other desirable organisms

Risk source

82. The source of potential harm for this postulated risk scenario is the introduced genes for increased abiotic stress tolerance and the HA-tag in GM canola plants.

Causal pathway

83. The GM canola would be grown at the trial sites. As the introduced genes for increased abiotic stress tolerance are controlled by constitutive promoters, the encoded proteins would expect to be produced in all tissues of the GM plants. People and desirable animals could be exposed to the GM plants containing the introduced proteins.

84. The GM canola would not be used for human food. Only authorised and trained trial staff would be permitted to deal with the GM plants and their seeds. Therefore, there is little potential for the public to be exposed to the GM plants grown at the trial sites.

85. Trial staff would handle the GM plant material produced by processing of the GM plants. Workers could be exposed to the introduced proteins by dermal contact and inhalation. Due to the small scale of the proposed trial, only a limited number of people would engage in dealings with the GM plant material.

86. The GM canola would not be used for animal feed and livestock would not be permitted to graze the trial sites. Therefore, livestock are not expected to be exposed to GM plants grown at the trial sites.

87. Desirable wild animals, such as native mammals and birds, could enter the trial sites and consume GM plants including seeds. The limited size and duration of the field trial would restrict the number of desirable wild animals exposed to GM plants grown at the trial sites.

Potential harm

88. Toxicity is the adverse effect(s) of exposure to a dose of a substance as a result of direct cellular or tissue injury, or through the inhibition of normal physiological processes (Felsot, 2000). Allergenicity is the potential of a substance to elicit an immunological reaction following its ingestion, dermal contact or inhalation, which may lead to tissue inflammation and organ dysfunction (Arts et al., 2006)

89. As discussed in Chapter 1, Section 4.3, although the introduced proteins for increased abiotic stress tolerance have not been assessed for toxicity and allergenicity by any authorities or animal feeding studies, bioinformatics studies by the applicant indicate that the proteins do not share relevant sequence homology with known toxins and allergens, indicating that they are not expected to be toxic or allergenic.

90. As mentioned in Chapter 1 Section 3, while non-GM canola is not generally regarded as allergenic or toxic to humans or animals, it does produce some allergens, toxins and anti-nutritional factors. As discussed in Chapter 1, Section 4.1, the protein encoded by the introduced gene for increased abiotic stress tolerance plays a role as a shuttle transport factor that facilitates nucleo-cytoplasmic trafficking, as well as roles in cell cycle regulation and division. Overexpression of the protein in plants has been associated with increased plant biomass in glasshouse trials. There is no reasonable expectation that the introduced genes for increased abiotic stress tolerance expressed in the GM canola would affect the pathways producing endogenous toxins or allergens in canola or lead to the production of novel toxins or allergens.

91. Some of the constructs introduced into the GM canola lines also have the HA-tag sequence from human influenza virus fused to the introduced genes for increased abiotic stress tolerance for detection of the tagged proteins. As discussed in Section 4.1, HA-tag is a widely used small peptide tag that does not normally disturb protein function and does not have a documented history of eliciting harmful immune responses. The HA-tag is not expected to alter the biological function of the GOI. The HA-tag sequence of 9 residues may not be accessible in native HA conformation, but it could potentially elicit an immune response under certain conditions, such as in the presence of an appropriate adjuvant. The HA-tag present in the GM canola is unlikely to meet such conditions and is therefore not expected to elicit a strong immune response. However, this is an area of uncertainty.

Conclusion

92. Risk scenario 1 is not identified as a substantive risk because the GM plant material would not be used as human food and animal feed, the small size and short duration of the proposed trial would restrict consumption of GM plant material by wild animals, the introduced proteins for increased abiotic stress tolerance are not expected to be toxic or allergenic, the HA-tag is not expected to elicit a strong immune response, and the limits and controls of the field trial would restrict exposure of people and desirable animals to the GM plants. Therefore, this risk could not be considered greater than negligible and does not warrant further detailed assessment.

2.1.2 Risk scenario 2

Risk source	Introduced genes for increased abiotic stress tolerance and the HA-tag
Causal pathway	⬇ Cultivation of GM canola at trial sites ⬇ Dispersal of GM seed outside trial limits ⬇ Establishment of populations of volunteer GM plants expressing the introduced genes in the environment ⬇
Potential harm	Increased toxicity or allergenicity for people OR Increased toxicity to desirable animals OR Reduced establishment or yield of desirable plants

Risk source

93. The source of potential harm for this postulated risk scenario is the introduced genes for increased abiotic stress tolerance and the HA-tag in GM canola plants.

Causal pathway

94. The GM canola would be grown at the trial sites. GM seeds could be physically dispersed outside the trial sites by human activity, animal activity, wind or water. GM seeds could also persist on trial sites after completion of the trial. These GM seeds could grow in the environment and establish populations of volunteer GM plants.

95. Viable GM canola seeds could be dispersed outside the trial sites by human activity, such as transport of seeds and movement of agricultural machinery. To minimise dispersal of GM seeds by human activity, the applicant proposes to clean all equipment used with the GM plants after use, and to transport all GM seed in accordance with the Regulator's Guidelines for the Transport, Storage and Disposal of GMOs.

96. GM seeds could be dispersed outside the trial sites by animal activity. Canola seeds have no specific adaptions, such as burrs or hooks, for dispersal by animals (OGTR, 2024). Dispersal of viable canola seed via endozoochory (consumption and excretion of seed) by birds only occurs at very low levels (Twigg et al., 2008; Woodgate et al., 2011). Canola seeds could be transported short distances by hoarding animals, such

as ants and mice. The applicant proposes that monitoring zones around trial sites would be inspected for volunteers.

97. Canola seeds lack specialised structures that would assist their dispersal by wind (OGTR, 2024). However, the GM canola may be windrowed prior to harvesting, and under strong wind conditions plant material could disperse outside trial sites. The applicant proposes that monitoring zones around trial sites would be inspected for volunteers.

98. GM canola seeds could be dispersed by water during flooding or heavy runoff, although seeds are unlikely to remain viable after prolonged exposure to water (OGTR, 2024). To minimise the potential for seed dispersal during flooding, the applicant proposes to locate the sites in areas which are not prone to flooding.

99. During harvest of the GM canola, a small percentage of the GM seeds are expected to be lost and to remain on the trial sites. Persistence of GMOs at the trial sites after the field experiment is finished could occur if seeds in the seed bank were dormant. Canola generally does not exhibit primary dormancy, but secondary dormancy has been described (OGTR, 2024). A study carried out in western Canada revealed that secondary seed dormancy prolonged persistence of volunteer canola plants (Gulden et al., 2003). Persisting canola seed banks have been shown to significantly contribute to the dynamics of feral canola populations (Pivard et al., 2008). A long-term monitoring study in Germany detected GM canola volunteers in arable fields for up to fifteen years after the field trial concluded, but did not detect spatial dispersion (Belter, 2016). In Australia, volunteers can be found for up to 3 years after growing canola due to persistence in seed banks, though the majority of volunteer seedlings emerge the year following a canola crop (AOF, 2014).

100. To minimise persistence of GM seeds on the trial sites, the applicant proposes to promote seed germination by light post-harvest tillage and irrigation. During a post-harvest monitoring period, the applicant would regularly inspect the trial sites and destroy any GM volunteers, until volunteers cease to emerge. The suitability of the proposed controls to manage GM seed dispersal and persistence is discussed in detail in Chapter 3, Section 3.1. These control measures are expected to minimise persistence of viable GM canola seeds on the trial sites.

101. If GM canola seeds were dispersed outside trial limits, it is unlikely that they would establish ongoing volunteer populations. Even in environments without active weed management, volunteer canola populations along transportation routes rely on recurrent spillages to persist (Yoshimura et al., 2006) and volunteer canola dispersed into natural areas was reported to rapidly become extinct (Busi and Powles, 2016). The genetic modifications for increased abiotic stress tolerance are not expected to affect the overall ability of volunteers to survive in the environment.

102. In agricultural areas of Australia where canola is grown, volunteer populations are controlled by a range of weed management measures. Effective methods for control of canola volunteers include grazing, mowing, cultivation and application of a range of knockdown or selective herbicides (AOF, 2019). The genetic modifications for increased abiotic stress tolerance are not expected to affect the susceptibility of GM volunteers to standard weed management measures. Although some of the canola lines will contain the *pat* gene and be tolerant to glufosinate herbicide, as discussed in Section 2.1, glufosinate herbicide is not used to control volunteer canola (AOF, 2019).

103. The applicant states that the introduced genes for increased abiotic stress tolerance are not known to play a role in seed dormancy or increased seed numbers. In glasshouse trials some increases in seed size were observed, but no changes in seed shattering characteristics. The applicant considers that increased abiotic stress tolerance may result in increased plant biomass and seed numbers under abiotic stress conditions but does not expect the introduced genes to increase persistence of the GM canola in the environment.

Potential harm

104. If the GM canola entered the Australian environment, the potential harms are increased toxicity or allergenicity to people, increased toxicity to desirable animals, reduced establishment or yield of desirable plants.

105. As discussed in risk scenario 1, no substantive risk was identified for increased toxicity or allergenicity of the GM canola for people or increased toxicity to desirable animals.

106. The genetic modifications for increased abiotic stress tolerance are expected to confer increased tolerance to environmental stresses, especially drought stress (Chapter 1, Section 4.1). Therefore, the GM canola volunteers could have increased persistence in the environment under abiotic stress conditions compared to non-GM canola volunteers.

107. Populations of volunteer GM canola could reduce establishment or yield of desirable plants. GM volunteers could directly compete with agricultural crops, pastures or native vegetation. GM volunteers could also reduce yield of commercial canola crops by providing a reservoir for pathogens, such as the important fungal diseases blackleg and stem rot (see Chapter 1, Section 5.2). No information could be found to suggest that the introduced genes are likely to make the GM canola more susceptible to pathogens.

108. Canola is considered a less competitive crop species than wheat or barley (GRDC, 2011), which are the main crops grown in eastern Australia (ABARES, 2021). All domesticated crop plant species are expected to be poor competitors with pasture species or established native vegetation. Therefore, canola volunteers have limited ability to compete with desirable plants. As discussed in Chapter 1, Section 4.4, the applicant expects that the GM canola plants might have better agronomic performance under abiotic stress conditions (such as drought) and plans to examine this intended trait in the field. However, even if the GM canola plants are more tolerant to abiotic stress conditions than non-GM canola, in order to increase weediness, this characteristic would need to be coupled with other mechanisms that increase spread and persistence in the environment, through changes in dispersal, establishment and survival. These characteristics would not reasonably be expected to change as a result of the introduced genes, therefore the introduced genes are not expected to increase the overall competitiveness of GM plants. In addition, no information could be found to suggest that the introduced genes would enable the GM canola to produce allelopathic substances which would negatively affect plant establishment around them.

Conclusion

109. Risk scenario 2 is not identified as a substantive risk because the proposed limits and controls of the field trial would minimise dispersal or persistence of GM seeds, GM canola is susceptible to standard weed management measures, the genetic modifications are not expected to increase toxicity or allergenicity, and the genetic modifications are not expected to increase the overall competitiveness of the GM canola with other plants. Therefore, this risk could not be considered greater than negligible and does not warrant further detailed assessment.

2.1.3 Risk scenario 3

Risk source	Introduced genes for increased abiotic stress tolerance and the HA-tag
Causal pathway	⬇ Cultivation of GM canola at trial sites ⬇ Pollen from GM plants dispersed outside the trial sites ⬇ Outcrossing with sexually compatible plants ⬇ Establishment of populations of hybrid GM plants expressing the introduced genes in the environment ⬇
Potential harm	Increased toxicity or allergenicity for people OR

	Increased toxicity to desirable animals OR Reduced establishment or yield of desirable plants

Risk source

110. The source of potential harm for this postulated risk scenario is the introduced genes for increased abiotic stress tolerance and the HA-tag in GM canola plants.

Causal pathway

111. The GM canola would be grown at the trial sites. Pollen from the GM plants could be transported out of the trial sites by wind or insect vectors and fertilise sexually compatible plants. Hybrid seeds containing the introduced genes could be harvested by farmers or could grow as volunteers.

112. It should be noted that vertical gene flow *per se* is not considered an adverse outcome, but may be a link in a chain of events that may lead to an adverse outcome.

113. Canola is primarily self-pollinating, but approximately 30% of seeds are produced by cross pollination. Outcrossing decreases rapidly with distance, with the majority of cross-pollination occurring over distances less than 10 m (OGTR, 2024). The introduced genes for increased abiotic stress tolerance are not expected to affect the pollen dispersal characteristics of the GM canola.

114. The GM canola could outcross with nearby canola crops or volunteers, if there is synchronicity of flowering. As discussed in Chapter 1, Section 5.4, canola can also occasionally hybridise with the related horticultural crops *B. juncea*, *B. oleracea* and *B. rapa* and the related weeds *H. incana*, *R. raphanistrum* and *S. arvensis.*

115. The applicant has proposed control measures to minimise pollen flow from GM plants growing on the trial sites to sexually compatible plants outside the trial sites (Chapter 1, Section 2.2). During flowering of the GM plants, each planting area would be surrounded by a pollen trap, monitoring zone and isolation zone. In addition, any GM volunteers growing on the trial sites after harvest would be destroyed prior to flowering. The suitability of the proposed controls to manage pollen flow is discussed in detail in Chapter 3, Section 3.1. These controls are expected to minimise pollen flow from the GM canola to sexually compatible non-GM plants outside the trial sites.

116. If pollen from GM plants fertilised plants in a commercial canola crop, hybrid GM seeds could be harvested for human food and animal feed, or be replanted in a crop. However, even in the complete absence of measures to restrict pollen flow, outcrossing rates between neighbouring commercial canola fields are less than 0.1% under Australian conditions (Rieger et al., 2002). Therefore, the planting seed described in this risk pathway could only contain a very low proportion of hybrid GM seed, so people and desirable animals could only be exposed to very low levels of the hybrid GMOs.

117. If pollen from GM plants fertilised sexually compatible plants growing as crops, volunteers or weeds, the hybrid GM seeds could grow as volunteers. Populations of hybrid GM volunteers could be consumed by desirable animals or could reduce the establishment or yield of desirable plants.

Potential harm

118. As discussed in risk scenario 1, no substantive risk was identified for increased toxicity or allergenicity of the GM canola for people or toxicity to desirable animals than non-GM canola. Similarly, in hybrids between the GM plants and sexually compatible plants, the same considerations as discussed in Risk Scenario 1 would apply so that production of novel allergens or toxins is highly unlikely.

119. As discussed in risk scenario 2, the GM canola may have enhanced tolerance to drought conditions but is not expected to increase the overall competitiveness than non-GM canola. Similarly, in hybrids between the GM plants and sexually compatible plants, the genetic modifications are not expected to confer an overall increased ability to compete with other plants.

Conclusion

120. Risk scenario 3 is not identified as a substantive risk because the controls of the field trial would minimise pollen flow to sexually compatible plants outside the trial sites. GM hybrids are not likely to differ from the GM canola, for which Risk scenarios 1 and 2 did not identify toxicity, allergenicity or weediness as substantive risks. Therefore, this risk could not be considered greater than negligible and does not warrant further detailed assessment.

Section 3 Uncertainty

121. Uncertainty is an intrinsic property of risk analysis and is present in all aspects of risk analysis. This is discussed in detail in the Regulator's Risk Analysis Framework document.

122. Uncertainty is addressed by approaches such as balance of evidence, conservative assumptions, and applying risk management measures that reduce the potential for risk scenarios involving uncertainty to lead to harm. If there is residual uncertainty that is important to estimating the level of risk, the Regulator will take this uncertainty into account in making decisions.

123. As field trials of GMOs are designed to gather data, there are generally data gaps when assessing the risks of a field trial application. However, field trial applications are required to be limited and controlled. Even if there is uncertainty about the characteristics of a GMO, limits and controls restrict exposure to the GMO, and thus decrease the likelihood of harm.

124. For DIR 205, uncertainty is noted particularly in relation to:

- the potential for increased toxicity of the GM canola to people or animals
- the potential for increased allergenicity of the GM canola to people
- the potential for immunogenic reactions to the HA-tag
- the potential for the genetic modifications to increase plant competitiveness and survival, particularly relating to increased tolerance to abiotic stresses.

125. Additional data, including information to address this uncertainty, may be required to assess possible future applications with reduced limits and controls, such as a larger scale trial or the commercial release of these GMOs.

126. Chapter 3, Section 4, discusses information that may be required for future release.

Section 4 Risk evaluation

127. Risk is evaluated against the objective of protecting the health and safety of people and the environment to determine the level of concern and, subsequently, the need for controls to mitigate or reduce risk. Risk evaluation may also aid consideration of whether the proposed dealings should be authorised, need further assessment, or require collection of additional information.

128. Factors used to determine which risks need treatment may include:

- risk criteria
- level of risk
- uncertainty associated with risk characterisation
- interactions between substantive risks.

129. Three risk scenarios were postulated whereby the proposed dealings might give rise to harm to people or the environment. In the context of the limits and controls proposed by the applicant, and considering both the short and long term, none of these scenarios were identified as substantive risks. The principal reasons for these conclusions are summarised in Table 4 and include:

- the GM plants would not be used as human food or animal feed
- limits on the size and duration of the proposed release

- controls proposed by the applicant to restrict the spread and persistence of the GM canola plants and their genetic material
- the products of the introduced genes are not expected to be toxic or allergenic
- GM canola volunteers could be controlled by standard weed management measures.

130. Therefore, risks to the health and safety of people, or the environment, from the proposed release of the GM canola plants into the environment are considered to be negligible. The *Risk Analysis Framework* (OGTR, 2013) which guides the risk assessment and risk management process, defines negligible risks as risks of no discernible concern with no present need to invoke actions for mitigation. Therefore, no additional controls are required to treat these negligible risks. Hence, the Regulator considers that the dealings involved in this proposed release do not pose a significant risk to either people or the environment.

Chapter 3 Risk management plan

Section 1 Background

131. Risk management is used to protect the health and safety of people and to protect the environment by controlling or mitigating risk. The risk management plan addresses risks evaluated as requiring treatment and considers limits and controls proposed by the applicant, as well as general risk management measures. The risk management plan informs the Regulator's decision-making process and is given effect through licence conditions.

132. Under Section 56 of the Act, the Regulator must not issue a licence unless satisfied that any risks posed by the dealings proposed to be authorised by the licence are able to be managed in a way that protects the health and safety of people and the environment.

133. All licences are subject to three conditions prescribed in the Act. Section 63 of the Act requires that each licence holder inform relevant people of their obligations under the licence. The other statutory conditions allow the Regulator to maintain oversight of licensed dealings: Section 64 requires the licence holder to provide access to premises to OGTR inspectors and Section 65 requires the licence holder to report any information about risks or unintended effects of the dealing to the Regulator on becoming aware of them. Matters related to the ongoing suitability of the licence holder must also be reported to the Regulator.

134. The licence is also subject to any conditions imposed by the Regulator. Examples of the matters to which conditions may relate are listed in Section 62 of the Act. Licence conditions can be imposed to limit and control the scope of the dealings and to manage risk to people or the environment. In addition, the Regulator has extensive powers to monitor compliance with licence conditions under Section 152 of the Act.

Section 2 Risk treatment measures for substantive risks

135. The risk assessment of risk scenarios listed in Chapter 2 concluded that there are negligible risks to people or the environment from the proposed field trial of GM canola. These risk scenarios were considered in the context of the scale of the proposed release (Chapter 1, Section 2.1), the proposed controls (Chapter 1, Section 2.2), and the receiving environment (Chapter 1, Section 5), and considering both the short and the long term. The risk evaluation concluded that no specific risk treatment measures are required to treat these negligible risks. Limits and controls proposed by the applicant and other general risk management measures are discussed below.

Section 3 General risk management

136. The limits and controls proposed in the application were important in establishing the context for the risk assessment and in reaching the conclusion that the risks posed to people and the environment are negligible. Therefore, to maintain the risk context, licence conditions have been imposed to limit the release to the proposed size, locations and duration, and to restrict the spread and persistence of the GMOs and their genetic material in the environment. The conditions are discussed and summarised in this Chapter and listed in detail in the licence.

3.1 Limits and controls on the release

137. Sections 2.1 and 2.2 of Chapter 1 list the limits and controls proposed by the applicant. Many of these are discussed in the three risk scenarios considered in Chapter 2. The appropriateness of these limits and controls is considered further in the following sections.

3.1.1 Consideration of limits proposed by the applicant

138. The applicant proposes that the field trial would take place between May 2025 and December 2030. This would limit the duration of the trial to five years and a few months. The GM canola would be grown at a maximum of three sites per year, with a planting area of up to 1.5 ha per site for the first year and up to 2 ha per site for the subsequent years. The small size and short duration of the trial would restrict the exposure of people and desirable animals to the GMOs (Risk scenario 1).

139. The applicant proposes that only authorised and trained people would be permitted to deal with the GMOs. Standard licence conditions included in the licence state that only people authorised by the licence holder are covered by the licence and permitted to deal with the GMOs. In addition, the licence holder must inform all people dealing with the GMOs of relevant licence conditions. These measures would ensure that the field trial is conducted in accordance with the specified limits and controls (important for all risk scenarios).

140. The licence limits the plants that can be intentionally grown in the planting area to the GMOs, non-GM canola, and any plants approved in writing by the Regulator. The applicant proposes to treat any non-GM canola plants grown in planting areas or pollen traps like the GMOs. These non-GM plants may be mingled with or fertilised by the GM plants and it is necessary to handle the non-GM plants in the same way as the GMOs to manage the dispersal or persistence of GM seed. This measure is therefore included in the licence.

3.1.2 Consideration of proposed controls regarding exposure to the GMOs

141. The applicant proposes that GM plants or products from the GM plants would not be used in human food or animal feed. The licence requires that GM plant material must not be used as food for humans or feed for animals. This condition would maintain the risk context by restricting the exposure of people and desirable animals to the GM canola by consumption (Risk scenario 1).

3.1.3 Consideration of proposed controls regarding pollen flow from the GMOs

142. The applicant proposes to surround the planting area with a 15 m pollen trap of non-GM canola plants, a 50 m monitoring zone and a 400 m isolation zone that starts from the outer edge of the planting area (Figure 2 in Chapter 1). The GM canola plants would not be planted at a trial site if any plants that are sexually compatible with canola were being grown in the monitoring or isolation zones. The pollen trap would be managed to flower at the same time as the GM canola plants. Pollen trap plants may provide sufficient forage for incoming pollinating insects so that they do not visit the GM plants, and any insects that reach the GM plants are expected to deposit most GM pollen on pollen trap plants while exiting the trial site. Pollen trap plants may also absorb some pollen dispersed by wind. As a non-GM pollen trap or buffer zone can also serve the same function as an unplanted monitoring zone (Hüsken and Dietz-Pfeilstetter, 2007), it is considered unnecessary to have both a pollen trap and a full-sized 50 m monitoring zone. In this trial setup, the licence condition requires a 15 m pollen trap and a 35 m monitoring zone. The use of a pollen trap justifies an isolation zone of 350 m and thus an overall distance of 400 m between the GMOs and any crops of related species.

143. Considering that there may be circumstances when a pollen trap may fail to function (e.g. failure to grow to a required density, or to form a continuous barrier, or to flower at the same time as the GM plants), the licence also includes an alternate option to control pollen flow by surrounding the planting area with a 50 m monitoring zone and a 950 m isolation zone (a combined isolation distance of 1 km from related species). This option was used for previous GM canola field trials and is considered an effective means of restricting pollen flow from canola (e.g. DIR 164 and DIR 188).

144. For either option, licence conditions require that the monitoring zone be inspected at least once every 35 days from 14 days prior to flowering of the GMOs until the GMOs are harvested, to ensure that it is free from any sexually compatible plants. The isolation zone would be inspected at least once every 35 days from 14 days prior to flowering of the GMOs until the GMOs complete flowering, to ensure that it is free from intentionally planted sexually compatible plants.

145. The proposed measures to control pollen flow would minimise outcrossing between the GMOs grown on the trial sites and sexually compatible plants growing outside the trial sites (Risk scenario 3).

146. After harvest of the trial sites, the applicant proposes to monitor the sites for volunteers (see Section 3.1.5). The applicant proposes to inspect at least once every 2 months, to find and destroy volunteers before they flower. The licences for other GM canola field trials (e.g. DIR 164 and DIR 188) require the licence holder to inspect for and destroy related species in the planting area and pollen trap while the GMOs are growing and carry out post-harvest inspection of the sites for canola volunteers at least once every 35 days. In southern parts of the Australian canola growing areas where the proposed trial sites are located, residual weeds including wild radish, wild turnip and charlock (wild mustard) are widely present (Llewellyn et al., 2016). As the applicant did not propose inspection for related species in the planting area and pollen trap while the GMOs are growing, it is possible that hybrids could be generated by crossing of the GMOs with any related species other than canola in the planting area and pollen trap. As it is possible that these hybrids may flower earlier than canola volunteers, this licence requires that these post-harvest inspections must be conducted at least once every 30 days, ensuring that canola volunteers/hybrids are detected and destroyed before flowering. This increased inspection frequency is consistent with the licence conditions for field trial of Indian mustard (DIR 188) and is considered an effective means of restricting pollen flow from GM canola volunteers/hybrids to plants outside the trial sites.

3.1.4 Consideration of proposed controls regarding dispersal of the GMOs

147. The applicant proposes that any equipment used with the GMOs would be cleaned as soon as practicable and before use for any other purpose, to avoid movement of viable plant material together with equipment. The applicant would contain the GM seeds during transport and storage in accordance with the Regulator's Guidelines for the Transport, Storage and Disposal of GMOs. The licence also includes a condition that the GM canola must be harvested separately from other crops, to avoid inadvertent seed mixing. These measures would minimise human-mediated dispersal of GM seeds (Risk scenario 2).

148. The applicant proposes to not locate trial sites in flood-prone areas in order to minimise the chance of viable plant material being washed away from the sites. This has been included as a condition in the licence. The licence also requires the trial sites to be located at least 50 m away from waterways as a standard licence condition for canola licences and that any extreme weather events must be reported to the Regulator. These measures would minimise dispersal of GM seeds by flooding (Risk scenario 2).

149. GM canola seeds could be dispersed short distances from the trial sites during sowing, windrowing or harvest activities; by pod shattering, by seed-hoarding behaviours of animals such as ants or rodents; or by strong winds or runoff after heavy rain. As described in Section 3.1.3, the planting areas would be surrounded by monitoring zones that are inspected while the GMOs are growing, so any volunteers growing from dispersed GM seeds during this period would be detected and destroyed. Specific conditions to minimise dispersal of GM plant material from windrowed plants by wind or rain have also been included in the licence. The applicant also proposes to inspect the monitoring zones after harvest to destroy any volunteers growing from dispersed GM seeds. As the short-distance seed dispersal mechanisms listed above are unlikely to transport seeds further than 10 m from the trial sites, the licence only requires post-harvest inspections of the innermost 10 m of the monitoring zone.

150. The licence includes additional conditions to manage short-distance dispersal of GM seeds. These include requiring the trial site to be cleaned within 14 days after harvest by a method that removes GM seeds from the soil surface, and requiring post-harvest inspections of any area used to clean equipment or any other area where GMOs are known to have dispersed. This combination of controls would minimise short-distance dispersal of GM seeds leading to establishment of volunteer populations outside the trial sites (Risk scenario 2).

3.1.5 Consideration of proposed controls regarding persistence of the GMOs

151. After harvest of each trial site, the applicant proposes to destroy GMOs not required for further evaluation or future trials. This would involve both cleaning the trial site within 14 days after harvest in a

manner that destroys any surviving GMOs, and destroying any harvested GM seed that is not required for experimentation or future planting.

152. The applicant has proposed that GMOs would be destroyed by herbicide application, root cutting and shredding/mulching, uprooting, light tillage to a depth of no more than 5 cm, burning/incineration, autoclaving, seed grinding, milling, or seed burial to a depth of at least 1 m. These methods are considered effective for rendering canola plants and/or seeds non-viable, and have been included in the licence. To ensure the effectiveness of destruction by seed burial, a licence condition specifies how this must be carried out, including a requirement that seeds must be sufficiently irrigated at time of burial to encourage decomposition.

153. To deal with the case of failed crops that are not harvested, licence conditions require that GMOs must be harvested or destroyed within eight months after planting, and that if all GMOs in a planting area have been destroyed, then the area is considered to have been harvested and cleaned.

154. The applicant proposes to monitor trial sites after harvest and destroy any volunteers that emerge. The areas that would be monitored are the planting area, the pollen trap, and other areas where GM seed may have dispersed, as discussed in Section 3.1.4. The frequency of inspections of the trial sites are discussed in Section 3.1.3. The proposed duration of monitoring by the applicant is at least 12 months, and until the site is free of volunteer canola plants for at least 6 months. In minimum-tillage Australian farms, the canola seedbank is reported to decline rapidly, and no viable seed was recovered from the seedbank by 2.5 years after canola harvest (Baker and Preston, 2008). Similarly, OGTR monitoring data for nine GM canola trial sites planted in 2015 found that in most sites no canola volunteers emerged more than 1 year after harvest and no volunteers emerged at any site more than 2.5 years after harvest. As discussed in Section 3.1.3, there is the potential that the GMOs may cross with other related species and produce hybrids when the GMOs are growing. However, the viable hybrid seeds, if any, are expected to be generated at a very low level and be detected and destroyed in 24 months. Therefore, the proposed duration for monitoring is at least 24 months, and until the site is free of volunteer canola plants for at least 12 months. This monitoring duration was required for previous GM canola field trials (e.g. DIR 164 and DIR 188) and is considered effective for managing persistence of canola/hybrid seed.

155. The applicant proposes shallow cultivation of the trial sites to encourage seed germination. The licence conditions require that tillage depth would be no greater than 5 cm, to avoid deep burial of seed that could induce dormancy. The first tillage would occur within 60 days after harvest and the final tillage would occur during the volunteer-free period prior to sign-off. To ensure that the final tillage produces conditions that are conducive to germination of volunteers, the licence requires this tillage to be followed by specified levels of rainfall or irrigation that provide sufficient moisture to the seedbank.

156. While the applicant has not currently proposed to plant post-harvest crops during the post-harvest monitoring period for each trial site, licence conditions are included to allow planting of plant crops permitted on GM brassica trial sites by the Regulator's Policy on Post-Harvest Crops. This will help to maintain the area in a manner appropriate to allow identification of volunteers.

157. The combination of control measures described in this section would minimise the persistence of GM seeds leading to establishment of GM volunteer populations in the environment (Risk scenario 2).

3.1.6 Summary of licence conditions to be implemented to limit and control the release

158. A number of licence conditions are imposed to limit and control the release, based on the above considerations. These include requirements to:

- limit the duration of the release to the period from May 2025 to December 2030
- limit the size of the release to a maximum of 3 sites per year, with a maximum area of 1.5 ha for each site in the first year and 2 ha for each site in the subsequent years
- limit the location of the release to nominated local government areas in NSW and SA
- not allow GM plant material to be used in human food or animal feed
- control pollen flow from the trial sites using one of the following options:

(a) surround the planting area with a pollen trap of 15 m, a monitoring zone of 35 m and an isolation zone of a further 350 m, or

(b) surround the planting area with a monitoring zone of 50 m and an isolation zone of a further 950 m

- treat any non-GM canola grown in planting areas or pollen traps like the GMOs
- harvest the GM canola separately from other crops
- clean equipment used with the GMOs before use for any other purpose
- transport and store the GMOs in accordance with the Regulator's guidelines
- locate trial sites at least 50 m from any natural waterways
- destroy all GMOs not required for further evaluation or future trials
- conduct post-harvest monitoring of the planting area and other areas where GM seeds may have been dispersed and destroy any volunteers that emerge
- post-harvest monitoring of the trial sites at least once every 30 days for at least 24 months after harvest and until the site is free of volunteers for at least 12 consecutive months
- conduct post-harvest tillage and irrigation of trial sites to encourage seed germination.

3.2 Other risk management considerations

159. All DIR licences issued by the Regulator contain a number of conditions that relate to general risk management. These include conditions relating to:

- applicant suitability
- contingency plans
- identification of the persons or classes of persons covered by the licence
- reporting requirements
- access for the purpose of monitoring for compliance.

3.2.1 Applicant suitability

160. In making a decision whether or not to issue a licence, the Regulator must have regard to the suitability of the applicant to hold a licence. Under Section 58 of the Act, matters that the Regulator must take into account include:

- any relevant convictions of the applicant
- any revocation or suspension of a relevant licence or permit held by the applicant under a law of the Commonwealth, a State or a foreign country and
- the capacity of the applicant to meet the conditions of the licence.

161. The licence conditions include a requirement for the licence holder to inform the Regulator of any information that would affect their suitability.

162. In addition, the licence holder must have access to an Institutional Biosafety Committee (IBC) and be an accredited organisation under the Act.

3.2.2 Contingency plan

163. The licence holder is required to submit a contingency plan to the Regulator before planting the GMOs. This plan would detail measures to be undertaken in the event of any unintended presence of the GM canola outside permitted areas.

164. Before planting the GMOs, the licence holder is also required to provide the Regulator with a method to reliably detect the GMOs or the presence of the genetic modifications in a recipient organism.

3.2.3 Identification of the persons or classes of persons covered by the licence

165. The persons covered by the licence are the licence holder and employees, agents or contractors of the licence holder and other persons who are, or have been, engaged or otherwise authorised by the licence holder to undertake any activity in connection with the dealings authorised by the licence. Prior to growing the GMOs, the licence holder is required to provide a list of people and organisations that will be covered by the licence, or the function or position where names are not known at the time.

3.2.4 Reporting requirements

166. The licence requires the licence holder to immediately report any of the following to the Regulator:

- any additional information regarding risks to the health and safety of people or the environment associated with the dealings
- any contraventions of the licence by persons covered by the licence and
- any unintended effects of the field trial.

167. A number of written notices are also required under the licence regarding dealings with the GMO, to assist the Regulator in designing and implementing a monitoring program for all licensed dealings. The notices include:

- expected and actual dates of planting
- details of areas planted to the GMOs
- expected dates of flowering
- expected and actual dates of harvest and cleaning after harvest and
- details of inspection activities.

3.2.5 Monitoring for compliance

168. The Act stipulates, as a condition of every licence, that a person who is authorised by the licence to deal with a GMO, and who is required to comply with a condition of the licence, must allow inspectors and other persons authorised by the Regulator to enter premises where a dealing is being undertaken for the purpose of monitoring or auditing the dealing. Post-release monitoring continues until the Regulator is satisfied that all the GMOs resulting from the authorised dealings have been removed from the release sites.

169. If monitoring activities identify changes in the risks associated with the authorised dealings, the Regulator may also vary licence conditions, or if necessary, suspend or cancel the licence.

170. In cases of non-compliance with licence conditions, the Regulator may instigate an investigation to determine the nature and extent of non-compliance. The Act provides for criminal sanctions of large fines and/or imprisonment for failing to abide by the legislation, conditions of the licence or directions from the Regulator, especially where significant damage to the health and safety of people or the environment could result.

Section 4 Issues to be addressed for future releases

171. Additional information has been identified that may be required to assess an application for a commercial release of the GM canola, or to justify a reduction in limits and controls.

172. This includes:

- compositional characterisation of the GM canola lines, particularly with respect to potential for increased toxicity
- biomolecular characterisation of the GM canola lines, particularly with respect to potential for increased allergenicity
- additional phenotypic characterisation of the GM canola lines, particularly with respect to increased tolerance to abiotic stresses leading to potential for increased weediness.

Section 5 Conclusions of the RARMP

173. The risk assessment concludes that the proposed limited and controlled release of GM canola poses negligible risks to the health and safety of people or the environment as a result of gene technology. These negligible risks do not require specific risk treatment measures.

174. However, licence conditions have been imposed to limit the release to the proposed size, location and duration, and to restrict the spread and persistence of the GMOs and their genetic material in the environment, as these were important considerations in establishing the context for assessing the risks.

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Appendix A: Summary of submissions from prescribed experts, agencies and authorities on the consultation RARMP

The Regulator received several submissions from prescribed experts, agencies and authorities[3] on the consultation RARMP. All issues raised in submissions relating to risks to the health and safety of people and the environment were considered in the context of the currently available scientific evidence and were used in finalising the RARMP that formed the basis of the Regulator's decision to issue the licence. Advice received is summarised below.

Submission	Summary of issues raised	Comment
1	Notes that the licence will prohibit the use of GM plant material in human food or animal feed. Does not have any further comments on the licence application at this stage.	Noted.
2	No advice or comments on the RARMP for DIR 205.	Noted.
3	Satisfied that there is no risk to the human population, animals or environment, and that the limits and controls ensure trial material not enter human or animal food chains and appear to be reasonable for the potential risks identified. Notes that the trial may lead to better yields under more adverse climates.	Noted.
4	Agrees that the proposed release poses negligible risk to human health and safety and the environment and noted all information provided in the consultation RARMP.	Noted.
	Suggests that the field trials are the appropriate time to include compositional/biochemical analysis of unintended effects caused by the insertion of the introduced DNA at various locations of recipient plant genome. This could include production of proteins other than those encoded by the introduced genes, resulting in increased allergy or toxicity. Suggests that these proteins could be identified by use of some contemporary techniques such as proteomics and metabolomics. States that there was recognition within the Scheme Review of the benefits of using field trials to achieve outcomes beyond agronomic assessment and to assess issues raised in the RARMP relevant to human health and the environment. Recommends including a requirement for compositional and biochemical analysis as part of the field trials to support a science-based assessment of unintended effects.	Unintended effects caused by the insertion of introduced DNA in plant genome are discussed in Chapter 2, Section 2.1 of the RARMP. Compositional and biochemical characterisation of the GM canola lines included in this application have been identified as issues to be addressed for future release in Chapter 3, Section 4 of the RARMP. This information may be required to assess possible future applications with reduced limits and controls, such as a larger scale trial or the commercial release of these GMOs. In the context of the limits and controls for DIR 205, this data is not required to manage the risks of this particular trial.
5	Agrees that the risk assessment identifies all plausible risk scenarios by which the proposed dealings could potentially give rise to risks relating to the health and safety of people or the environment.	Noted.

[3] Prescribed expects, agencies and authorities include GTTAC, State and Territory Governments, Australian Government agencies and the Minister for the Environment.

Submission	Summary of issues raised	Comment
	Agrees that the measures to limit and control the release are appropriate for the trial. Agrees with the overall conclusion of the RARMP.	
	Recommends that the Regulator should further consider risks associated with the human influenza hemagglutinin peptide tag (HA-tag).	The RARMP is amended, with new text about the human influenza HA-tag added in Chapter 1, Section 4.1 and discussion of risks associated with the HA-tag included in Risk Scenario 1.